



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request:

Clinical Mythteries: A Video Game About Clinical Trials

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on June 13, 2012, page 35407 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

PROPOSED COLLECTION: *Title:* Clinical Mythteries: A Video Game About Clinical Trials. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* New England Research Institutes as a contractor for the National Heart Lung and Blood Institute is planning to create an engaging, informational “serious video game” for adolescents about clinical studies which: 1) incorporates core learning objectives; and 2) dispels misconceptions. Two types of information collection are planned: • usability testing to understand game-play/usability. This information will be collected by focus group and will be digitally recorded 90 minute groups. • A pre/post randomized trial to measure change in knowledge. This information will be collected electronically through on-line questionnaire.

The game will be incorporated with a larger initiative to provide information about clinical research (<http://www.nhlbi.nih.gov/childrenandclinicalstudies/index.php>). *Frequency of Response:* Once. *Affected Public:* Individuals. *Type of Respondents:* Adolescents – aged 8-14. The annual reporting burden is as follows: *Estimated Number of Respondents:* 280; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours Per Response:* Wave 1 – 90/60 (1.5 hours), Wave 2 - 80/60 (1.33 hours); and *Estimated Total Annual Burden Hours*

Requested: 378. The annualized cost to respondents is estimated at: \$3,783. There are no Capital Costs to report.

The Operating Costs to collect this information is estimated at \$42425.00.

(NOTE: The following table is acceptable for the Respondent and Burden Estimate information, if appropriate, instead of the text as shown above.)

Form Name	Type of Respondents	Estimated Number of Respondents	Estimated Number of Responses per Respondent	Average Burden Hours Per Response	Estimated Total Annual Burden Hours Requested
Qualitative Focus Group Discussion Guide and screener	Adolescents – Wave one	30	1	90/60 (1.5 hours)	45
Screen pre post eval	Adolescents – Wave two	250	1	80/60 (1.33 hours)	333
	Total	280	378

REQUEST FOR COMMENTS: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

DIRECT COMMENTS TO OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to [202-395-6974](tel:202-395-6974), Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Victoria Pemberton, RNC, MS, CCRC, National Heart, Lung and Blood Institute, 6701 Rockledge Drive, Rm. 8109, Bethesda, MD 20892, or call non-toll-free number (301) 435-0510 or E-mail your request, including your address to: pembertonv@mail.nih.gov

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: February 8, 2013_____

Michael Lauer,
Director, Division of Cardiovascular Diseases
National Heart, Lung, and Blood Institute, NIH

Dated: February 12, 2013_____

Lynn Susulske
NHLBI Project Clearance Liaison
National Institutes of Health

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